

## 90-DAY RESPONSE

DCI Number: GDCI-043901-1668

## Data Call-In Information

Company Name	PAN ASIAN CHEMICALS INC.
Company Address	5444 WESTHEIMER ROAD, #1570 HOUSTON, TX 77056
DCI Type	Generic
Issued Date	09/21/2017
90 Day Response Deadline	12/30/2017
CRM Information	opp_ad_reevaluation_DCI_team@epa.gov
Chemical Name	Glutaraldehyde
Chemical Number	043901

## 90-Day Response Information

Tracking Number	CDX_DCI_2018_000094
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## DCI Level Documents

File Name	File Type	MRID	CBI	Submitted Date
GDCI-043901-1668 Cover Letter.pdf	Submission Cover Letter	N.A.	N	01/19/2018

## EPA Product Registration Number(s)

88951 4	I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."
88951 1	I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."
88951 5	I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."
88951 2	I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."

## Guideline Requirement Number(s)

Guideline Requirement Number - 850.4400

Study Title	Aquatic Plant Toxicity Using Lemna spp
Protocol	N
Target Submission Date	09/21/2018
Use Pattern	R; S; T; U; V; X; Z
Test Substance	TGAI
Time Frame	12 month(s)
Footnote(s)	1. Based on the results of a previous study on green algae indicating the EC50 is less than 1 mg/l (1 ppm), tier II data on a vascular aquatic plant (850.4400; Lemna spp.), freshwater diatom (GLN 850.4500; Navicula pelliculosa), and marine diatom (GLN 850.4500; Skeletonema costatum) are required.
Registrant Response	Offer to Cost Share

## Uploaded Documents

File Name	File Type	MRID	CBI	Submitted Date
EPA Form 8570-32 for G15.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	01/19/2018
DOW Offer to pay attachment to EPA Form 8570-34.pdf	General Correspondences	N.A.	N	01/19/2018

Guideline Requirement Number - 850.4500				
Study Title	Algal Toxicity			
Protocol	N			
Target Submission Date	09/21/2018			
Use Pattern	R; S; T; U; V; X; Z			
Test Substance	TGA1			
Time Frame	12 month(s)			
Footnote(s)	1. Based on the results of a previous study on green algae indicating the EC50 is less than 1 mg/l (1 ppm), tier II data on a vascular aquatic plant (850.4400; Lemna spp.), freshwater diatom (GLN 850.4500; Navicula pelliculosa), and marine diatom (GLN 850.4500; Skeletonema costatum) are required. 3. Green algae study not required, since EPA has in-house study MRID 45609401. Fresh Water Algal Growth Inhibition Test with Glutaraldehyde 50% M.H.J. Migchielsen, 2001. 4. In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See Final Test Guidelines; OCSPP 850 Series; Notice of Availability 77 FR 38282, June 27, 2012. <a href="https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028">https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028</a> .			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
EPA Form 8570-32 for G25.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	N	01/19/2018
BASF Offer to pay attachment to EPA Form 8570-34.pdf	General Correspondences	N.A.	N	01/19/2018
Guideline Requirement Number - 875.1400				
Study Title	Inhalation exposure--indoor			
Protocol	Y			
Target Submission Date	09/21/2019			
Use Pattern	R; S; T; U; V; X; Z			
Test Substance	TGA1			
Time Frame	24 month(s)			
Footnote(s)	5. Inhalation exposure scenarios for handlers (875.1400) include: open pour application; paint application; machinist trigger spray and wipe application for medical premises disinfection; spray, mop, and sponge application for agricultural, commercial, and food processing premises disinfection; and mop, wipe, and trigger spray application of preserved cleaning products. Inhalation exposure scenarios for post-application (875.2500) include: painting; hard surface disinfection; laundry detergent; and metal working fluids. For similar scenarios, results of 875.2500 may be used to estimate exposures and satisfy the data requirements for 875.1400. 6. Protocols must be approved by the Agency prior to the initiation of the study.			
Registrant Response	Waiver Request			
Comments	Not applicable because product is solely used outdoors for closed delivery oilfield applications.			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
GDCI-043901-1668 Waiver Request.pdf	Waiver Request	N.A.	N	01/19/2018
Guideline Requirement Number - 875.2500				
Study Title	Inhalation exposure			
Protocol	Y			
Target Submission Date	09/21/2019			
Use Pattern	R; S; T; U; V; X; Z			

Test Substance	TGAI			
Time Frame	24 month(s)			
Footnote(s)	<p>5. Inhalation exposure scenarios for handlers (875.1400) include: open pour application; paint application; machinist trigger spray and wipe application for medical premises disinfection; spray, mop, and sponge application for agricultural, commercial, and food processing premises disinfection; and mop, wipe, and trigger spray application of preserved cleaning products. Inhalation exposure scenarios for post-application (875.2500) include: painting; hard surface disinfection; laundry detergent; and metal working fluids. For similar scenarios, results of 875.2500 may be used to estimate exposures and satisfy the data requirements for 875.1400.</p> <p>6. Protocols must be approved by the Agency prior to the initiation of the study.</p>			
Registant Response	Waiver Request			
<b>Uploaded Documents</b>				
File Name	File Type	MRID	CBI	Submitted Date
GDCI-043901-1668 Waiver Request.pdf	Waiver Request	NA	N	01/19/2018
<b>Guideline Requirement Number - SS-Migration</b>				
Study Title	Migration studies			
Protocol	Y			
Target Submission Date	09/21/2018			
Use Pattern	R; S; T; U; V; X; Z			
Test Substance	TGAI			
Time Frame	12 month(s)			
Footnote(s)	<p>2. For the three highlighted scenarios (i.e., commercial assessment, paper manufacturing, and food processing plants) the residue screening level default at 100% of the application rate triggered a risk of concern (see Section 3.2.1); and therefore, a migration study is required to refine the potential exposures. If the surface residues measured after a potable water rinse (PWR) no longer trigger a risk concern no additional migration data are needed. However, if the measured surface residues with a PWR still trigger a risk concern, then a second tier migration study measuring the transfer of residues from surfaces to food items is needed.</p> <p>6. Protocols must be approved by the Agency prior to the initiation of the study.</p>			
Registant Response	Waiver Request			
<b>Uploaded Documents</b>				
File Name	File Type	MRID	CBI	Submitted Date
GDCI-043901-1668 Waiver Request.pdf	Waiver Request	NA	N	01/19/2018
<b>Submitter Information</b>				
Submitter	James Wrubel			
Submitted Date	01/19/2018			
Additional Contact(s)	ddb@panasianchem.com; jdw@panasianchem.com			